5. 510(K) Summary

This document was prepared in accordance with 21 CFR 807.92.

Section (a)

(1) Name of the submitter: Nihon Seimitsu Sokki Co., Ltd.
Address: 2508-13 Nakago, Shibukawa, Gunma 377-0293, Japan
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Contact person: Mitsuo Kanai
Date of documentation: September 14, 2011

(2) Trade name of the device: Blood Pressure Monitor WSK-1011
Common name: Blood pressure monitor
Classification: Noninvasive blood pressure measurement system, DXN, 870.1130, Class II

(3) Predicate devices: Wrist blood Pressure Monitor, Model WS-1100/WS-1100PV, K080177, Nihon Seimitsu Sokki, Co., Ltd.

(4) Description of the device:
Blood Pressure Monitor WSK-1011 is an automatic sphygmomanometer to be used in a homecare environment. Blood pressure, systolic and diastolic, and pulse rate are taken at wrist non-invasively using oscillometric method, which is one of the most common methods with recent automatic sphygmomanometer that determines blood pressure and pulse rate with oscillations against cuff applied to measurement site. The device consists of the main unit and the cuff that is applicable to wrist circumference between 4.9 and 8.9 inches (between 125 and 225 mm), singly mounted. The device is powered by two AAA alkaline batteries. The device not only determines blood pressure and pulse rate from oscillations but also analyses pulse wave and determines whether measurement was made with or without body movement and regularity of pulse rhythm. Besides these auxiliaries, user can get pulse pressure value and blood pressure level according to WHO guideline also on the display. User can chose to activate clock function of the device to review measured readings with measurement date and time.

(5) Intended use of the device:

WSK-1011 system is intended for noninvasive measurement of systolic and diastolic blood pressure, determination of pulse rate and calculation of pulse pressure in adults in a homecare environment.

The device features include display of irregular pulse rhythm detection, classification display of measured blood pressure values against WHO (World Health Organization) guidelines, display of body movement detection and two memory account to save measurement results.

The indication for use of WSK-1011 system is not exactly same with but similar to the predicate device. The fundamental intended use, which is to measure adults' blood pressure non-invasively in home care environment, remains the same. The difference between the indications for use of the subject device and the predicate device lies in supplemental product features; some features of the predicate device are not provided with the new device and some new features are introduced with the subject device. As demonstrated in relevant sections of this submission, these features are concluded not to affect the device safety and effectiveness.

(6) Technological characteristics of the subject device and the predicate device:

The subject device holds the same technological fundamentals with the predicate device. Both devices consist of the single-mounted main unit and cuff for wrist and powered with two AAA alkaline batteries. The patient contacting materials used for the subject device had been used with the predicate device and these materials do not go through any different process from the predicate devices. The list of patient contacting materials and components is included in the relevant section of this application.

(7) The following Device comparison table,shows the details of differences between the subject device and the claimed predicats.

Device comparison table

	WSK-1011, the subject device	WS-1100/WS-1100PV (K080177)	Note
Intended use	WSK-1011 system is intended for noninvasive measurement of systolic and diastolic blood pressure, determination of pulse rate and calculation of pulse pressure in adults in a homecare environment. The device features include display of irregular pulse rhythm detection, classification display of measured blood pressure values against WHO (World Health Organization) guidelines, display of body movement detection and two memory account to save measurement results.	WS-1100/WS-1100PV system is intended for noninvasive measurement of systolic and diastolic blood pressure and determination of pulse rate in adults in a homecare environment. The device features include the display of irregular pulse rhythm detection, the classification display of measured blood pressure values against the guideline by World Health Organization or equivalent guideline, the personal setting for individual blood pressure target values, the two memory banks to save the measurement results with date and time of measurement and the transferring the saved results to personal computers.	
Operation principle	Oscillometric method	Oscillometric method	Same
Pressure indication range	3 to 300 mmHg	0 to 300 mmHg	
Measurement site and cuff size	Wrist Regular size (Approximately 4.9 to 8.9 inches; 125 to 225 mm)	Wrist Regular size (Approximately 4.9 to 8.0; 125 to 205 mm)	Same
Power source	2 AAA alkaline batteries	2AAA alkaline batteries	Same
Inflation	Automatic air pump	Automatic air pump	Same
Deflation	Automatic electric control valve	Automatic electric control valve	Same
Exhaust	Automatic quick exhaust valve	Automatic quick exhaust valve	Same
Display	15 digits liquid crystal display Date and time display	15 digits liquid crystal display Date and time display	Same
Device setting by the user	Date and time	Date and time Personal target limits of blood pressure values	
Memory features	2 memory banks to save 60 easurement results with date and time, when the clock is activated; the saved readings can be intentionally deleted by the user.	2 memory banks to save 60 blood pressure and pulse rate readings each with date and time; saved reading(s) can be intentionally deleted by the user. Mode to view AM and PM readings separately Exporting saved readings to personal computers using the designated USB cable	
Main unit	Size: approximately W;2.76 x D;1.06 x H;2.76 inches Weight: approximately 3.9 oz. Material: ABS and PMMA	Approximate size: W; 2.79, D; 2.56, H; 1.18 inches Approximate weight: 4.09 oz. Material: ABS and PMMA	-----
Cuff type	Preformed nylon cuff	Preformed nylon cuff	Same

Section (b)

(1) Non-clinical tests

The subject device was evaluated in accordance with IEC and SP-10 not only to demonstrate the substantial equivalence but also to establish the better safety. This is why some reference standards were added to test the subject device when compared to the predicated devices. The detailed information of reference standards is provided in the relevant sections of this submission.

(2) Clinical tests

No clinical test report is submitted because differences between the subject device and the predicate devices do not affect clinical performance.

(3) Conclusions drawn from non-clinical tests

It is concluded from the non-clinical tests conducted that the subject device is not only as safe and as effective as the predicate devices but is also safer and more effective than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 2 4 2012

Nihon Seimitsu Sokki Co., Ltd.
c/o Mr. Koji Kubo
Manager
Cosmos Corporation
6-5-3 Beaunce Honkomagome 2F, Honkomagome
Bunkyo-ku, Tokyo
JAPAN 113-0021

Re: K112690
Trade/Device Name: Blood Pressure Monitor, Model WSK-1011
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: February 14, 2012
Received: February 16, 2012

Dear Mr. Kubo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number: K112690

Device Name: Blood Pressure Monitor WSK-1011

Indications for Use:

Wrist Blood Pressure Monitor WSK-1011 is intended for noninvasive measurement of systolic and diastolic blood pressure, determination of pulse rate and calculation of pulse pressure in adults in a homecare environment.

The device features include display of irregular pulse rhythm detection, classification display of measured blood pressure values against WHO (World Health Organization) guidelines, display of body movement detection and two memory account to save measurement results.

Prescription Use_____ AND / OR Over-The Counter Use ___X___

(Per 21 CFR 801.109 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Device

510(k) Number K112690